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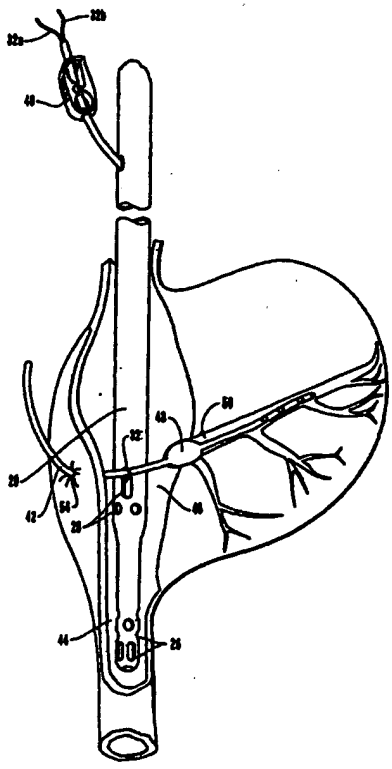
(54) Title: VENOUS RETURN CATHETER WITH ANCHOR MEANS AND METHOD FOR USE

(57) Abstract

This invention is a two stage venous catheter (20) which removably anchors a retrograde cardioplegia catheter (42) in place within the coronary sinus of a patient. A suture loop (32) extends therefrom in the region of the right atrium near the coronary sinus. The suture loop (32) is tightened around a retrograde cardioplegia catheter (42), and thus helps prevent inadvertent dislodgement of the cardioplegia catheter (42) from the coronary sinus. The cardioplegia catheter (42) which is to be anchored in place by the suture loop (32) includes a balloon (48) positioned within the coronary sinus which blocks the coronary ostium. Alternatively, an elongated balloon (148) which substantially blocks the coronary veins emptying near the coronary ostium, is utilized.



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VENOUS RETURN CATHETER WITH ANCHOR MEANS AND METHOD FOR USE

BACKGROUND OF THE INVENTION

1. The Field of the Invention

The present invention is directed generally to methods and apparatus for performing cardiac surgical procedures. More specifically the present invention is related to methods and apparatus for providing cardiopulmonary bypass and retrograde cardioplegia during cardiac surgical procedures.

2. The Relevant Technology

It is customary during certain cardiac surgical procedures to interrupt the normal function of the heart. Currently, the most common method for stopping the heart during surgery is the infusion of a cold cardioplegia fluid, which both cools the heart and stops it from beating. Cardioplegia (literally, "heart-stop") may be administered to the heart through the arteries in the normal direction of blood flow, referred to as "antegrade" administration, through the veins in the opposite direction of normal blood flow, referred to as "retrograde" administration, or in a combination of retrograde and antegrade administration.

Antegrade cardioplegia is conventionally administered by inserting a single needle into the aorta and injecting cardioplegia solution which then flows to the muscle tissue of the heart, the "myocardium," through the coronary arteries. However, since atherosclerosis may have already decreased the flow potential through the coronary arteries, cardioplegia may not reach the myocardium in sufficient volume to offer protection. Further, in aortic valve surgery, direct injection of the cardioplegic solution to both coronary ostia is required. This obstructs the already limited operative field on the one hand, and may also be associated with a risk of injury to the coronary ostia with resulting ostial stenosis, on the other hand. Such complication might require further operative correction.

Retrograde cardioplegia is administered by inserting the distal end of an elongated catheter within the portion of the heart known as the coronary sinus. The coronary sinus is normally the drainage avenue into the right atrium for deoxygenated blood from the vessels supplying the myocardium. During retrograde administration, cardioplegia solution is forced through the coronary sinus in the direction opposite the normal flow of blood through the coronary veins. This procedure is known as "Retrograde Coronary Sinus Perfusion" (RCSP).

Conventional catheters for administering RCSP are equipped at their distal end with either a manually-inflatable or a self-inflatable balloon. Manual inflation entails that fluid from a remote location be introduced such as through an inflation lumen into the balloon. Self-inflating balloons are in fluid communication with the cardioplegia infusion lumen of the catheter and are inflated with cardioplegia solution. When inflated, both types of balloon engage the wall of the coronary sinus to form a seal.

During RCSP it is of concern to keep the distal balloon firmly situated within the coronary sinus. The wall of the coronary sinus is slippery and expandable, and it tapers in a manner such that the sinus vessel becomes narrower in the direction in which the balloon is advanced during insertion. Thus, one conventional approach is to place the balloon well into the coronary sinus to ensure good retention. However, several veins open into the coronary sinus very near the point at which the coronary sinus opens into the right atrium. If the balloon is inserted too deeply, it may exclude these veins from perfusion. Further, in at least about 20% of the cases the catheter dislodges notwithstanding the deep insertion due to lifting and manipulating of the heart during surgery.

Another problem associated with conventional retrograde approaches is that cardioplegia being pumped into the coronary sinus may bypass a portion of the circulatory system of the heart and leak back into the coronary sinus through one of the coronary veins. The cardioplegic solution being pumped into the coronary sinus will seek the path of least resistance via collateral circulation through a network of tiny vessels interconnecting the coronary veins and the coronary sinus. The coronary veins emptying proximal to the balloon, that is, in the direction of the coronary ostium, such as the middle cardiac vein, act as an avenue for shunting cardioplegia from collateral veins into the coronary sinus and right atrium. An additional contributing factor to the path of least resistance is that the right atrium has negative pressure which pulls the cardioplegia in that direction. This shunting of cardioplegia is known as the "steal syndrome" and it might effectively steal approximately 25-35% of the volume of cardioplegia from its intended route, thus compromising protection of the myocardium.

SUMMARY OF THE INVENTION

The present invention relates to new and useful apparatus and methods for securing a retrograde cardioplegia catheter in place within the coronary sinus. A unique two-stage venous catheter anchors the retrograde cardioplegia catheter, and as a result the retrograde cardioplegia catheter balloon need not be inserted distally into the coronary sinus to preclude inadvertent movement and displacement as is conventionally required

with retrograde cardioplegia catheters. Instead, the anchoring of the cardioplegia catheter to the two-stage venous catheter permits positioning of the balloon at a proximal location in the coronary sinus even if the retrograde cardioplegia catheter is of the conventional design with a balloon at the distal segment of the catheter. This task is facilitated by first inserting the conventional retrograde cardioplegia catheter into the coronary sinus, then by manual palpation in the back of the heart along the coronary sinus, the retrograde cardioplegia catheter is gently pulled until the balloon takes a position close to the coronary ostium. At this point, the retrograde cardioplegia catheter is anchored to the two-stage venous catheter.

Alternatively, a retrograde catheter with a larger diameter and more proximally located balloon may be utilized. Such a catheter requires less manipulation for positioning of the balloon close to the coronary ostium. Further, the larger diameter balloon provides a better seal of the proximal coronary sinus which typically has a greater diameter than its distal segment.

In one embodiment of the present invention, the two-stage venous catheter includes a suture loop which tightens around a retrograde catheter to anchor it in place. The suture loop extends proximally from a side tube which acts like a tourniquet and distally from one of the drainage holes on the two-stage venous catheter. The suture loop is attached to an umbelical tape segment which is easily grasped by an instrument such as a tonsil clamp inserted into the right atrium through the "purse-string" suture made in the right atrium for insertion of the retrograde cardioplegia catheter. The umbelical tape is also attached to the origin of the tourniquet side tube by means of a prolene suture.

In one embodiment of the method of the present invention, the umbelical tape is grasped by a tonsil clamp, and the prolene suture is cut with scissors close to a purse string suture previously made in the right atrium. The umbelical tape is pulled out through the purse string suture and the suture loop is delivered outside the heart. The umbelical tape is then cut leaving the suture loop intact. The retrograde cardioplegia catheter is then inserted through the purse string suture. Once the retrograde cardioplegia catheter is properly positioned within the coronary sinus, the suture loop which is outside of the right atrium is passed around the proximal portion (the portion outside of the heart) of the retrograde cardioplegia catheter. The suture loop slides around the cardioplegia catheter and into the right atrium when pulled gently outwardly from the tourniquet side tube. The tourniquet side tube is then clamped to maintain the hold of the suture loop around the cardioplegia catheter.

Using the methods and apparatus of the present invention, the cardioplegia catheter is very securely anchored to the two-stage venous catheter. Once the balloon on the cardioplegia catheter is inflated, the coronary ostium is sealed and cardioplegia solution is optimally distributed. Once the balloon is inflated, the position of the balloon can easily be felt by the surgeon's hand, and adjustments in the balloon position can be made prior to anchoring of the retrograde cardioplegia catheter to the two-stage venous catheter.

In another embodiment of the present invention, a retrograde cardioplegia catheter with an elongated balloon is utilized for occluding the veins draining into the coronary sinus near the coronary ostium. The elongated balloon helps avoid shunting of the cardioplegia solution from the myocardium. It will be appreciated, however, that the longer balloon may interfere with perfusion of side branches in the coronary sinus as compared with a more proximal balloon of larger diameter situated immediately within the coronary sinus.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to more fully understand the manner in which the above-recited and other advantages of the invention are obtained, a more particular description of the invention will be rendered by reference to a specific embodiment thereof which is illustrated in the appended drawings. Understanding that these drawings depict only a typical embodiment of the invention and are not therefore to be considered to be limiting of its scope, the invention in its presently understood best mode for making and using the same will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Figure 1 is a partial perspective view of one preferred embodiment of the present invention.

Figure 2 is another view of the embodiment illustrated in Figure 1 with the temporary restraining suture detached from the tourniquet side tube.

Figure 3 is an *in situ* illustration of the embodiment of the present invention from Figure 1 with a retrograde catheter secured thereto.

Figure 4 is an *in situ* illustration of the embodiment of the present invention from Figure 1 with another embodiment of a retrograde catheter secured thereto.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A primary concern of every cardiac surgeon is protection of the myocardium (the muscle tissue of the heart) during cardiac surgical procedures. A preferred method for protecting the myocardium entails arresting the normal function of the heart by means of

administration of cardioplegia solution. One conventionally preferred mode of administration of cardioplegia solution, known as retrograde coronary sinus perfusion ("RCSP"), is through a catheter positioned within the coronary sinus which delivers cardioplegia to the heart in a retrograde direction, that is, opposite the normal flow of blood through the heart.

Conventional retrograde cardioplegia catheters include balloons for occluding the coronary sinus. In an effort to prevent displacement of the catheter which occurs in approximately 20% of the cases, the occlusion balloon is conventionally positioned deep within the coronary sinus. However, such deep placement within the coronary sinus permits the coronary veins emptying proximal to the balloon, such as the middle cardiac vein, to act as an avenue for shunting cardioplegia through the path of least resistance through the venous collaterals to the coronary sinus and the right atrium.

The present invention is directed to an apparatus and method for providing venous return during cardiopulmonary bypass while enabling a retrograde cardioplegia catheter to be anchored in place within the coronary sinus. The inventive structure of the present invention impedes displacement of the retrograde cardioplegia catheter and helps eliminate the problems associated with inadequate distribution of cardioplegia through the heart. The present invention is also directed to a method for use of the venous return-retrograde catheter combination.

A conventional venous return catheter collects and routes de-oxygenated blood to a cardiopulmonary bypass machine for oxygenation. Upon proper placement of the venous return catheter, venous blood is collected from the inferior vena cava and the right atrium. An example of a conventional venous return catheter is disclosed in United States Patent No. 4,639,252, which is hereby incorporated herein by reference.

A preferred venous return catheter in accordance with the present invention is illustrated by reference numeral 20 in Figure 1. Venous return catheter 20 includes a hollow interior lumen running the substantial length thereof for draining deoxygenated blood from the heart and directing it to a cardiopulmonary bypass machine for oxygenation. Venous return catheter 20 further includes a proximal portion 22 and a distal portion 24. The terms "proximal" and "distal" are used herein with reference to the catheter: proximal is in reference to the direction of the portion of the catheter which is outside the patient, and distal refers to the direction of the portion of the catheter which is inside the patient. These terms are not necessarily used herein in one manner conventional to surgeons wherein the heart is the point of reference.

The distal portion 24 of the venous return catheter is designed to extend into the

inferior vena cava of a patient, and preferably includes a plurality of distal drainage openings 26. These distal drainage openings 26 provide drainage for venous blood into the venous return catheter 20 from the inferior vena cava. The preferred placement of the distal portion of the venous return catheter in the inferior cava is better illustrated in Figures 3 and 4, to be described in more detail hereinbelow.

Returning to Figure 1, and in a proximal direction from the distal drainage openings 26, a plurality of proximal drainage openings 28 preferably circumscribe the venous return catheter. These proximal drainage openings provide drainage for venous blood from the right atrium into the catheter. Drainage from the superior vena cava is also provided by these proximal drainage openings. The preferred placement of the proximal drainage openings within the right atrium is better illustrated in Figures 3 and 4, which will be described in more detail hereinbelow.

The venous return catheter of the present invention includes a unique structure which removably anchors a retrograde cardioplegia catheter in place in the coronary sinus of a patient. In one presently preferred embodiment of the present invention such as that depicted in Figure 1, this unique structure comprises anchor means 30.

In a preferred embodiment, anchor means comprises suture loop 32, grasping member 34, and temporary restraining suture 36, each of which will be described in more detail hereinbelow. It will be appreciated that other structural elements that provide means for anchoring a retrograde catheter in place in the coronary sinus are within the scope of the present invention.

The suture loop is designed to tighten around a retrograde catheter such that it retains the catheter stably in place in the coronary sinus and adjacent the venous return catheter. The suture loop preferably comprises 2-0 silk, although other surgical materials which provide appropriate strength and flexibility would be within the scope of the present invention.

The suture loop 32 preferably extends distally from one of the proximal drainage openings of the venous catheter as illustrated in Figure 1. Alternatively, an additional access hole is provided in the two-stage venous catheter specifically for the suture loop.

In the embodiment of the present invention depicted in Figure 1, the suture loop extends distally only slightly from one of the proximal drainage openings. The remaining length of the suture loop extends proximally through tourniquet side tube 38, as illustrated by ends 32a, 32b. Tourniquet side tube 38 is provided along the venous return catheter proximal from the proximal drainage openings 28, and extends laterally therefrom. Preferably, the tourniquet side tube is located outside of the right atrium, a

few centimeters from the point of entry of the two-stage venous catheter into the right atrium. The tourniquet side tube preferably comprises a smaller diameter internal lumen than the venous return catheter. The internal lumen of the tourniquet side tube preferably opens into the internal lumen of the two-stage venous return catheter.

The length of the suture loop is preferably variable such that it can be pulled into an enlarged loop through which a retrograde catheter may extend, and then tightened securely around the catheter, as will be described in more detail hereinbelow with respect to the method of the present invention. The added length of the distal portion of the suture loop is drawn from the proximal portion thereof which extends through the tourniquet side tube 38 as schematically illustrated in Figures 1 and 2 by proximal ends 32a, 32b.

Further, in the presently preferred embodiment of the present invention, clamp 40 is provided along tourniquet side tube 38 to releasably maintain the suture loop at a particular length. When the clamp is in an open position, the size and placement of the suture loop can be manipulated. When the clamp is closed, the suture loop cannot be enlarged or tightened. Figures 3 and 4, which will be described in more detail hereinbelow, illustrate tightened suture loop 32, the length of which is secured by closed clamp 40. It will also be appreciated that other means for maintaining the suture loop at a particular length would be within the scope present invention. In a preferred embodiment of the present invention depicted in Figure 1, attached to the suture loop is a grasping member with a tangible surface area which permits a tonsil clamp or other instrument to pull the suture loop for enlarging the size thereof. For example, when the grasping member 34 is pulled, the suture loop 32 is enlarged as illustrated in Figure 2. In one preferred embodiment, the grasping member comprises umbelical tape. It will be appreciated that other grasping means which facilitate access to the suture loop would be within the scope of the present invention.

In the embodiment of the present invention depicted in Figure 1, the suture loop and grasping member are releasably retained to the venous catheter via temporary restraining suture 36. As illustrated in Figure 1, the preferred temporary restraining suture is attached to the grasping member 34 and extends around the tourniquet side tube 38. It will be appreciated that other temporary restraining means are within the scope of the present invention. Alternatively, the grasping member itself is removably secured to the side tube to temporarily restrain the suture loop. Alternatively, the temporary restraining suture or the grasping member may be temporarily secured to the two-stage venous catheter at a separate location.

Temporary restraining suture 36 preferably comprises 4-0 prolene suture. The 4-0 prolene suture is easily cut or otherwise detached from around the tourniquet side tube 38 to release the grasping member 34. For example, Figure 2 illustrates the 4-0 prolene suture 36 detached from the tourniquet side tube 38.

Figure 3 is an illustration of a two-stage venous catheter 20 in accordance with the present invention and a retrograde catheter 42, positioned *in situ* in the heart. The distal drainage openings 26 of the two-stage venous catheter extend into the inferior vena cava 44. The proximal drainage openings 28 are positioned within the right atrium, represented generally by numeral 46. The retrograde catheter 42 passes through purse string suture 54 into the right atrium and includes balloon 48 situated within the coronary sinus 50 and blocking the coronary ostium.

Conventionally, balloons are positioned such that occlusion of the coronary sinus is substantially distal from the coronary ostium thereby reducing the potential slippage of the catheter out of the coronary sinus. However, this conventional placement allows the coronary veins emptying proximal to the balloon to act as an avenue for shunting cardioplegia back into the right atrium rather than through the heart muscle where it is needed for protective purposes. A retrograde cardioplegia catheter with a balloon which blocks these veins and the coronary ostium precludes the cardioplegia from travelling along the path of least resistance to the right atrium. More cardioplegia is available to the myocardium, providing increased protection. Thus, in an alternate embodiment of the present invention illustrated in Figure 4, retrograde catheter 142 includes balloon 148 which is substantially elongated and extends into the coronary sinus. This embodiment actually blocks veins emptying very close to the coronary ostium, such as the greater cardiac vein, represented generally by numeral 52.

In both Figures 3 and 4, suture loop 32 is secured around retrograde catheter 42, 142 and clamp 40 is closed such that balloon 48,148 is retained within the coronary sinus 50 during the surgical procedure. It should be appreciated that other retrograde catheters such as those conventionally used by those of skill in the art are within the scope of the present invention. As mentioned previously hereinabove, manual palpation along the coronary sinus in the back of the heart will help positioning the balloon of a conventional retrograde cardioplegia catheter in the proximal portion of the coronary sinus, near the coronary ostium. Once in proper position, the retrograde cardioplegia catheter can be anchored to the two-stage venous catheter.

The present invention is also directed to methods for using the unique anchoring means. One preferred embodiment of the method of the present invention will be

described herein for the purpose of illustration, but it should be appreciated that this method is not meant to be limiting of the present invention.

A two-stage venous catheter 20 in accordance with the present invention is positioned within the right atrium 46 and inferior vena cava 44 as depicted in Figures 3 and 4. A purse string suture 54 is made in right atrium for insertion of the retrograde catheter 42, 142. The retrograde catheter is inserted and positioned within the coronary sinus 50. The temporary restraining suture 36 is detached from the tourniquet side tube 38, as illustrated in Figure 2. A surgical instrument such as a tonsil clamp is inserted through the purse string to grip the grasping member 34. The clamp is pulled from the purse string suture bringing the suture loop 32 along with it, and the grasping member is removed and discarded. The suture loop is pulled over the retrograde catheter.

In contrast, in an alternate embodiment of the method of the present invention, the suture loop is secured around the retrograde catheter during insertion of the retrograde catheter into the right atrium, and tightened once the retrograde catheter is properly positioned within the coronary sinus. However, unlike the preferred method described above, this method entails essentially blindly attempting to secure the suture loop around the catheter, which is a less reliable and efficient method than simply pulling the loop over the catheter.

The suture loop 32 is tightened around the retrograde catheter 42,142 such as by pulling the proximal portion through the tourniquet side tube 38. Upon proper securement of the loop around the retrograde catheter and proper positioning thereof, the clamp 40 on the tourniquet side tube is closed or locked into place for the substantial duration of the surgical procedure during which the retrograde catheter is utilized. For removal of the retrograde catheter, the clamp is simply unlocked and the loop is loosened, thereby releasing the secure anchoring of the retrograde catheter.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A two-stage venous catheter for use during surgical procedures involving cardiopulmonary bypass, said catheter comprising means for anchoring a retrograde catheter in position within a coronary sinus.

2. A catheter as recited in Claim 1, wherein said anchor means comprises a suture loop.

3. A catheter as recited in Claim 2, wherein said anchor means further comprises a means for grasping said suture loop, said grasping means being removably attached to said suture loop.

4. A catheter as recited in Claim 3, wherein said anchor means further comprises means for temporarily restraining said suture loop, said temporary restraining means being removably attached to said grasping means.

5. A catheter as recited in Claim 4, further comprising a tourniquet side tube, said tourniquet side tube being disposed proximally along said two-stage venous catheter and extending laterally therefrom.

6. A catheter as recited in Claim 5, wherein said tourniquet side tube further includes a clamp.

7. A catheter as recited in Claim 5, wherein said suture loop comprises a proximal portion disposed through said tourniquet side tube.

8. A catheter as recited in Claim 1, further comprising:

a) a distal portion suitable for placement within an inferior vena cava, said distal portion being provided with a plurality of distal drainage openings for draining blood from said inferior vena cava; and

b) a proximal portion in fluid communication with said distal portion, said proximal portion being provided with a plurality of proximal drainage openings suitable for draining blood, said proximal drainage openings capable of being positioned within the right atrium of a patient.

9. A catheter as recited in Claim 8, wherein said anchor means is disposed distally through one of said plurality of proximal drainage openings.

10. A two-stage venous catheter for use during surgical procedures involving cardiopulmonary bypass, said catheter comprising:

a) a distal portion suitable for placement within an inferior vena cava, said distal portion being provided with a plurality of distal drainage openings for draining blood from said inferior vena cava;

b) a proximal portion in fluid communication with said distal portion, said proximal portion being provided with a plurality of proximal drainage

openings suitable for draining blood, said proximal drainage openings capable of being positioned within the right atrium of a patient; and

c) means for anchoring a retrograde cardioplegia catheter in position within a coronary sinus, said anchor means being disposed within said catheter near said proximal portion.

11. A catheter as recited in Claim 10, wherein said anchor means comprises a suture loop.

12. A catheter as recited in Claim 11, wherein said suture loop is disposed distally through one of said plurality of proximal drainage openings.

13. A catheter as recited in Claim 11, further comprising a tourniquet side tube, said tourniquet side tube being disposed proximally along said two-stage venous catheter and extending laterally therefrom.

14. A catheter as recited in Claim 13, wherein said tourniquet side tube further includes a clamp.

15. A catheter as recited in Claim 13, wherein said suture loop comprises a proximal portion disposed through said tourniquet side tube.

16. A catheter as recited in Claim 11, wherein said anchor means further comprises a means for grasping said suture loop, said grasping means being removably attached to said suture loop.

17. A catheter as recited in Claim 16, wherein said anchor means further comprises means for temporarily restraining said suture loop, said temporary restraining means being removably attached to said grasping means.

18. A catheter as recited in Claim 10, wherein the retrograde cardioplegia catheter includes an inflatable balloon, and wherein said means for anchoring the retrograde cardioplegia catheter anchors the inflatable balloon in position within the coronary sinus near the coronary ostium.

19. A two-stage venous catheter for use during surgical procedures involving cardiopulmonary bypass, said catheter comprising:

a) a distal portion suitable for placement within an inferior vena cava, said distal portion being provided with a plurality of distal drainage openings for draining blood from said inferior vena cava;

b) a proximal portion in fluid communication with said distal portion, said proximal portion being provided with a plurality of proximal drainage openings suitable for draining blood, said proximal drainage openings capable of being positioned within the right atrium of a patient; and

c) a suture loop disposed within said catheter near said proximal portion.

20. A catheter as recited in Claim 19, wherein said suture loop is disposed distally through one of said plurality of proximal drainage openings.

21. A catheter as recited in Claim 19, further comprising a tourniquet side tube, said tourniquet side tube being disposed proximally along said two-stage venous catheter and extending laterally therefrom.

22. A catheter as recited in Claim 21, wherein said tourniquet side tube further includes a clamp.

23. A catheter as recited in Claim 21, wherein said suture loop comprises a proximal portion disposed through said tourniquet side tube.

24. A catheter as recited in Claim 19, further comprising a grasping member being removably attached to said suture loop.

25. A catheter as recited in Claim 24, further comprising a temporary restraining suture being removably attached to said grasping member.

26. A catheter as recited in Claim 19, wherein the retrograde cardioplegia catheter includes an inflatable balloon, and wherein said suture loop anchors the inflatable balloon in position within the coronary sinus near the coronary ostium.

27. A system for use during cardiopulmonary bypass procedures, said system comprising:

a) a retrograde cardioplegia catheter; and

b) a venous return catheter, said venous return catheter comprising means for anchoring said retrograde cardioplegia catheter in place within a coronary sinus.

28. A system according to Claim 27, wherein said anchor means comprises a suture loop.

29. A system according to Claim 28, wherein said venous return catheter comprises a plurality of proximal drainage openings.

30. A system according to Claim 29, wherein said suture loop is disposed distally through one of said plurality of proximal drainage openings.

31. A system according to Claim 28, further comprising a tourniquet side tube, said tourniquet side tube being disposed proximally along said two-stage venous catheter and extending laterally therefrom.

32. A system according to Claim 31, wherein said suture loop comprises a proximal portion disposed through said tourniquet side tube.

33. A system according to Claim 28, wherein said anchor means further comprises a means for grasping said suture loop, said grasping means being removably attached to said suture loop.

34. A system according to Claim 33, wherein said anchor means further comprises means for temporarily restraining said suture loop, said temporary restraining means being removably attached to said grasping means.

35. A system as recited in Claim 27, wherein the retrograde cardioplegia catheter includes an inflatable balloon, and wherein said means for anchoring the retrograde cardioplegia catheter anchors the inflatable balloon in position within the coronary sinus near the coronary ostium.

36. A method for stabilizing a retrograde cardioplegia catheter within a coronary sinus, comprising the steps of:

a) positioning a retrograde cardioplegia catheter within the coronary sinus of a patient; and

b) removably anchoring said retrograde cardioplegia catheter to a venous return catheter positioned within the right atrium of said patient.

37. A method as recited in Claim 36, wherein said retrograde cardioplegia catheter is anchored to said venous return catheter by means of a suture loop.

38. A method as recited in Claim 37, wherein said retrograde cardioplegia catheter is passed through said suture loop upon insertion of said retrograde cardioplegia catheter into the heart of a patient.

39. A method as recited in Claim 37, wherein said suture loop is passed over said retrograde cardioplegia catheter after insertion of said retrograde cardioplegia catheter into the coronary sinus of a patient.

40. A method as recited in Claim 36, wherein the retrograde cardioplegia catheter includes an inflatable balloon, and wherein the inflatable balloon is anchored in position within the coronary sinus near the coronary ostium.

41. A method for stabilizing a retrograde catheter within a coronary sinus, comprising the steps of:

a) positioning a venous return catheter within the right atrium of a patient, said venous return catheter comprising:

i) a distal portion suitable for placement within an inferior vena cava, said distal portion being provided with a plurality of distal drainage openings for draining blood from said inferior vena cava;

ii) a proximal portion in fluid communication with said distal portion, said proximal portion being provided with a plurality of proximal drainage openings suitable for draining blood, said proximal drainage openings capable of being positioned within the right atrium of a patient; and

iii) means for anchoring a retrograde catheter in position within a coronary sinus, said anchoring means being disposed within said catheter proximal from said distal portion;

b) positioning a retrograde cardioplegia catheter within the coronary sinus of a patient; and

c) removably anchoring said retrograde cardioplegia catheter to said venous return catheter.

42. A method as recited in Claim 41, wherein the retrograde cardioplegia catheter includes an inflatable balloon, and wherein the inflatable balloon is anchored in position within the coronary sinus near the coronary ostium.

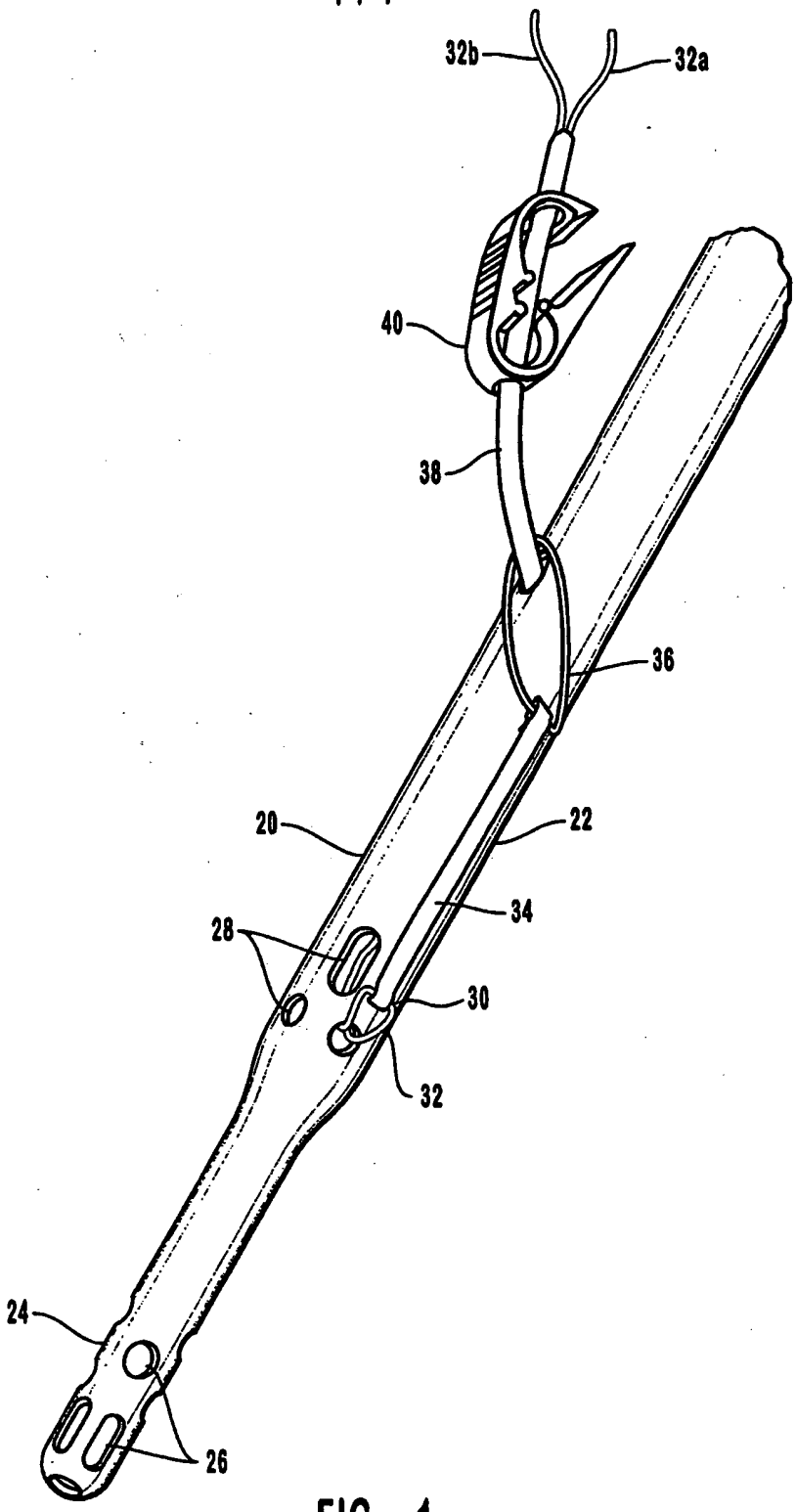

FIG. 1

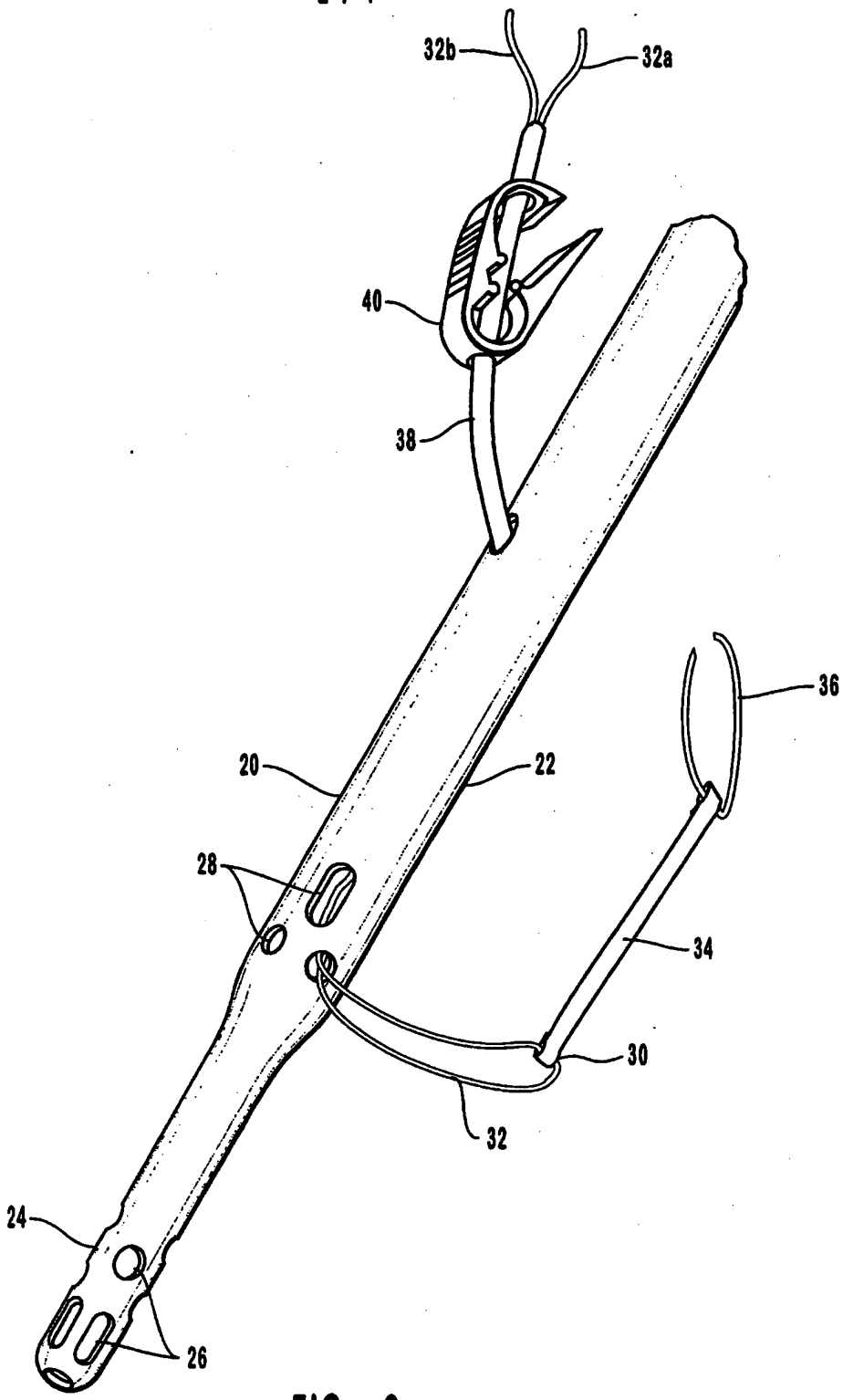

FIG. 2

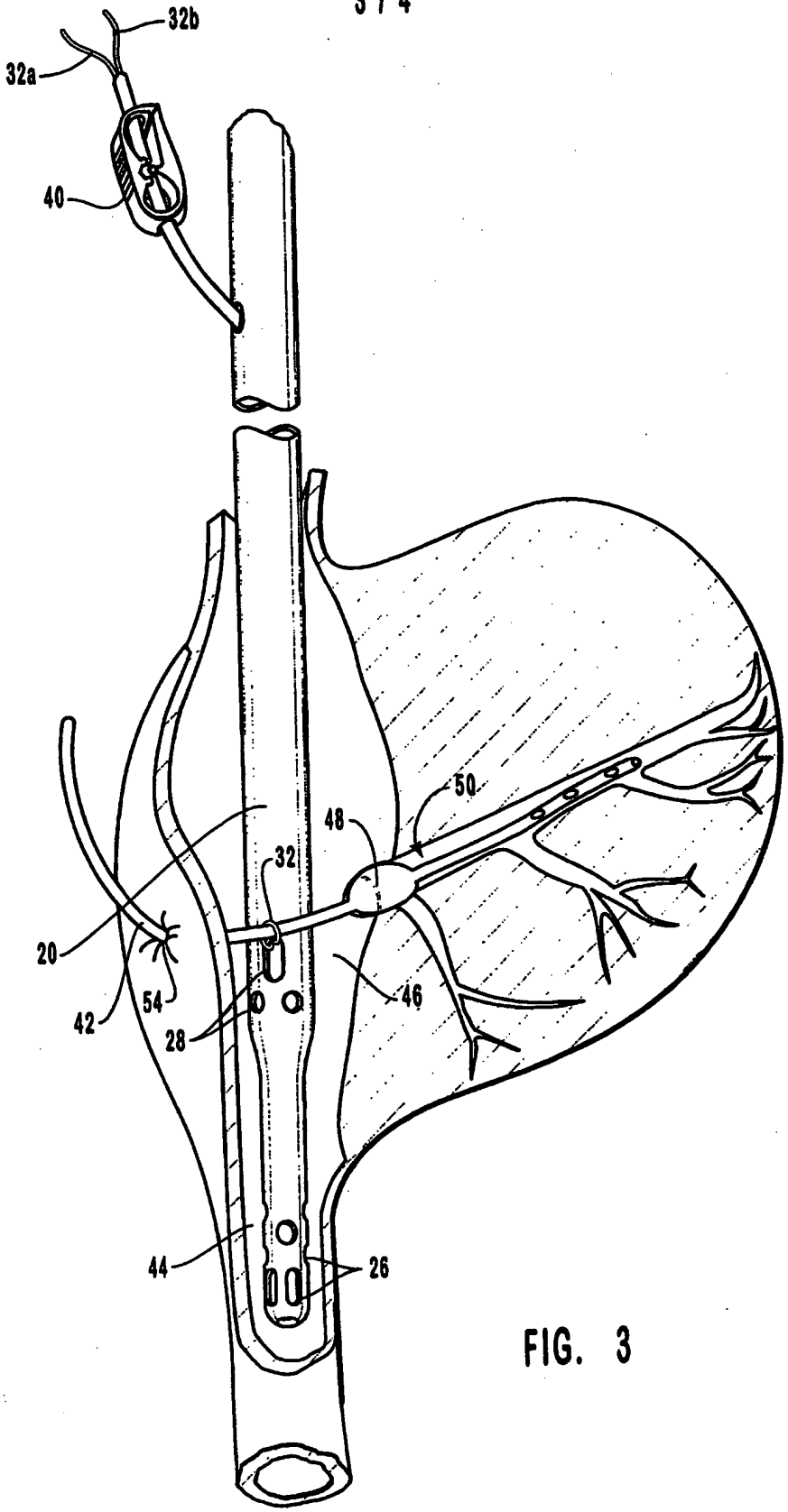

FIG. 3

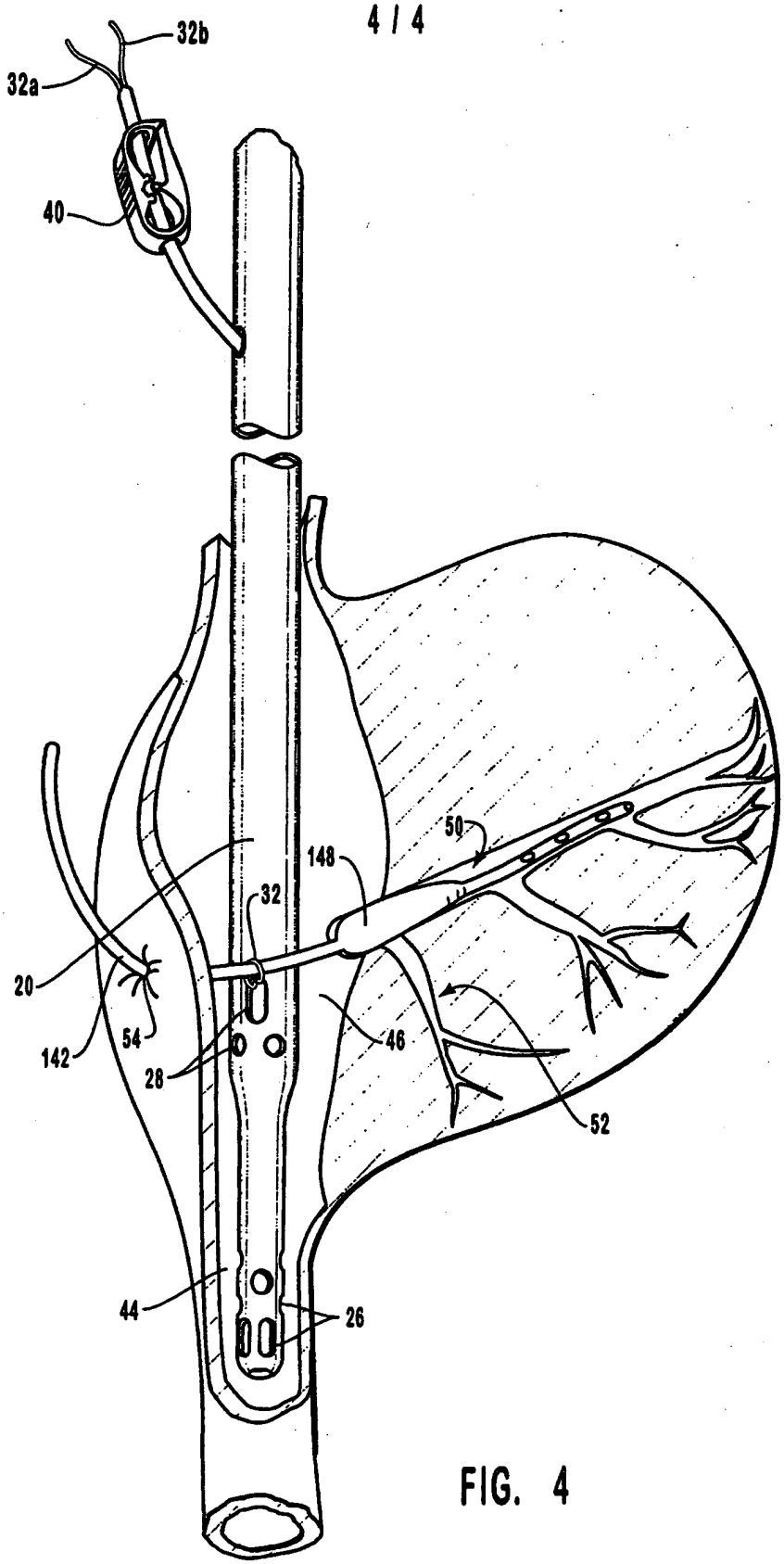

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/19224

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 5/32
US CL :604/174
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/4. 96. 174. 264. 500. 508; 606/191,194

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,718,692 A (SCHON et al.) 17 February 1998, Figs 1, 3, , and related text.	1, 8, 27
—		—
Y		35
Y	US 4,548,597 A (NELSON) 22 October 1985, col. 1 lines 46-56; Fig. 1, and related text.	36, 40
A	US 4,639,252 A (KELLY et al.) 27 January 1987, entire document.	1, 10, 19
P,A	US 5,913,842 A (BOYD et al.) 22 June 1999, entire document.	1-42

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 OCTOBER 1999	17 NOV 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MICHAEL J. HAYES Telephone No. (703) 305-5873

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